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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,987	07/12/2001	Michael G. Douglas	42108/26146	3819

21888 7590 01/29/2003  
THOMPSON COBURN, LLP  
ONE FIRSTAR PLAZA  
SUITE 3500  
ST LOUIS, MO 63101

EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/29/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Vacated # 6



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# Office Action Summary

Application No.

09/904,987

Applicant(s)

DOUGLAS ET AL.

Examiner

Samuel W Liu

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17 and 47-48 drawn to composition capable of solubilizing an inappropriate folded and/or aggregated protein in the solution comprising chemical functional groups attached to the composition, buffering agents and target proteins, classified in class 546, subclass 193 and class 530, subclass 350.
- II. Claims 18-46, drawn to method of *in vitro* solubilization of an inappropriate folded and/or aggregated protein and method of treating an animal by administering therapeutically effective amount of the composition capable of preventing or reversing assembly or aggregation of conformationally altered protein, classified in class 436, subclass 15 and 176, 514, subclass 228.8, and class 604, subclass 48.

The inventions are distinct each from the other because of the following reasons:

Invention I and Invention II are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in the invention I can be used in a materially different process; picolinic acid and its analogues can be used as an anti-virus effector (see Fernandez-Pol, J. A. et al. (2001) Anticancer Res. Vol. 21, 37773-37776), for example.

#### ***Required Election***

This application contains claims directed to the following patentable distinct inventions. The compositions solubilize inappropriate folded and/or aggregated proteins that are disease-related.

With respect to Group I, e.g. Claims 2, 17 and 47 recite a structure where there are four "R"-groups (R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub>) selected from patentably distinct groups. Under 35 U.S.C. 121 as part of the response to this restriction, applicants are required to (a) select one chemical group for

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each of R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub>; (b) a specific cation; (c) one buffering reagent; (d) disease state affected by the claimed composition (see Claim 13); (e) one sequence (see Claim 14, each sequence is physically, chemically, and biologically distinct, absent evident to the contrary); and (f) a group to which cells the therapeutic composition is administered (see Claim 43).

Note that this is not a species election but a requirement for restriction under 121 because: (1) the R-groups are different as an oligopeptide is not equivalent to a small non peptidic organic R-group, such as -CH<sub>3</sub>;

(2) each cation is different with respect to sphere of hydration as well as net charge;

(3) each buffering agent is different with respect to chemical structure and properties, e.g. fractionated vegetable oils versus hydroxypropyl methylcellulose (Claim 7).

(4) each disease is different with different modes of treatment and expected outcomes and

(5) each peptide is different, as for example SEQ ID No.1 has 43 residues whereas SEQ ID NO. 2 has 77 residues.

(6) each group selected from Claim 43 are different species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, or/and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached at (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL

April 17, 2002

Christopher S. F. Low

CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600